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10/553,430

12/26/2006

Christopher Hug

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EXAMINER

DUTT, ADITI

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/553,430 | Applicant(s) HUG ET AL. | |
| | Examiner Aditi Dutt | Art Unit 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/26/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 30-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 30-33, 39-41, drawn to a method of assessing the efficiency of a modulator of a T-cadherin polypeptide for the treatment of obesity.

Group II, claim(s) 34-38, drawn to a method of assessing the efficiency of a modulator of a T-cadherin polypeptide for the treatment of type II diabetes.

Group III, claim(s) 42-50, 52, 54-55, 57-58, drawn to a method of identifying candidate drugs for the treatment of a disorder comprising contacting T-cadherin polypeptide with a candidate T-cadherin agonist modulator.

Group IV, claim(s) 42-47, 50-58, drawn to a method of identifying candidate drugs for the treatment of a disorder comprising contacting T-cadherin polypeptide with a candidate T-cadherin antagonist modulator.

Group V, claim(s) 59-64, drawn to a method of treating a disorder comprising administration of a composition comprising a T-cadherin agonist modulator to an individual.

Group VI, claim(s) 59-61, 63-65, drawn to a method of treating a disorder comprising administration of a composition comprising a T-cadherin antagonist modulator to an individual.

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2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of assessing the efficiency of a modulator of a T-cadherin polypeptide for the treatment of obesity, which is not required by the other methods of Groups II-VI.

Group II recites the special technical feature of assessing the efficiency of a modulator of a T-cadherin polypeptide for the treatment of type II diabetes, which is not required by the other methods of Groups I, III-VI.

Group III recites the special technical feature of identifying candidate drugs for the treatment of a disorder comprising contacting T-cadherin polypeptide with a candidate T-cadherin agonist modulator, which is not required by the other methods of Groups I, II, IV-VI.

Group IV recites the special technical feature of identifying candidate drugs for the treatment of a disorder comprising contacting T-cadherin polypeptide with a candidate T-cadherin antagonist modulator, which is not required by the other methods of Groups I-III, V-VI.

Group V recites the special technical feature of treating a disorder comprising administration of a composition comprising a T-cadherin agonist modulator to an individual, which is not required by the other methods of Groups I-IV, VI.

Group VI recites the special technical feature of treating a disorder comprising administration of a composition comprising a T-cadherin antagonist modulator to an individual, which is not required by the other methods of Groups I-V.

3. ***Species Election***

A) Disorder

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) Metabolic
- b) Gynecologic
- c) Chronic Inflammatory
- d) Liver
- e) Renal

The claims are deemed to correspond to the species listed above in the following manner:

Claims 42, 59

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above disorders have distinct pathology and the treatment would involve varying levels of drug sensitivity and therapeutic success. For example, the special technical feature of Metabolic disorder is not shared by the other disorder species.

B) Metabolic Disorder

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- f) Obesity
- g) Type II Diabetes
- h) Insulin resistance

- i) Hypercholesterolemia
- j) Hyperlipidemia
- k) Dyslipidemia
- l) Syndrome X
- m) Anorexia and Cachexia

If applicant elected the 'Metabolic Disorder' group as the species of Disorder, applicant is further required to select a more specific metabolic disorder.

The claims are deemed to correspond to the species listed above in the following manner: Claims 44-47, 50, 60, 63 and 64.

The following claim(s) are generic: 42 and 59.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above metabolic disorders have distinct pathology and the treatment would involve varying levels of success. For example, the special technical feature of Obesity is not shared by the other metabolic disorders.

C) Candidate Modulator

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- n) Natural ligands
- o) Small molecules
- p) Aptamer
- q) Antisense mRNA
- r) Small Interfering RNA
- s) Soluble form of T-cadherin
- t) Antibody

The claims are deemed to correspond to the species listed above in the following manner: Claims 43 and 49

The following claim(s) is generic: 42

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above modulators have distinct structural and functional characteristics having distinct mechanism of action. For example, the special technical feature of natural ligands is not shared by the other candidate modulators.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. In response to this Office Action/Election requirement, applicant must elect one from Groups I-VI and must additionally elect a species from the disorder, metabolic disorder and candidate modulator, for consideration.

5. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Advisory Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037.

The examiner can normally be reached on M-F.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
21 December 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649

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